U.S. DEPARTMENT OF COMMERCE ATENT AND TRADEMARK OFFICE

## INFORMATION DISCLOSURE **STATEMENT**

Docket Number: 1662/63202

Application Number 10/781,543

Filing Date

February 17, 2004

Examiner Not Yet Assigned Art Unit 1614

Invention Title

MENTHOL SOLUTIONS OF DRUGS

Inventors

FLASHNER-BARAK et al.

Address to:

Commissioner for Patents P.O. Box 1450

Alexandria, VA 22313-1450

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA

22313-1450 on

Date: 5/25/04 Reg. No. 30,333

Signature: Mary C. Whence

Sir:

- 1. In accordance with the duty of disclosure under 37 C.F.R. § 1.56 and in conformance with the procedures of 35 U.S.C. §§ 1.97 and 1.98 and M.P.E.P. § 609, attorneys for Applicants hereby bring the following references to the attention of the Examiner. These references are listed on the attached modified PTO Form No. 1449. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom. The filing of this Information Disclosure Statement and the enclosed PTO Form No. 1449, shall not be construed as an admission that the information cited is prior art, or is considered to be material to patentability as defined in 37 C.F.R. § 1.56(b).
- 2. A copy of each patent, publication or other information listed on the modified PTO form 1449 is enclosed unless otherwise noted.
- It is believed that no fees are due in connection with this Information Disclosure Statement. 3. However, should any fees be due, the Commissioner is authorized to charge Deposit Account No. 11-0600 for such fees. A copy of this communication is enclosed for charging purposes.

Dated:

5/24/04

By: Craig L. Puckett (Reg. No. 43,023)

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**CUSTOMER NUMBER 26646** 

## **U. S. PATENT DOCUMENTS**

| EXAMINER<br>INITIAL | PATENT<br>NUMBER | PATENT<br>DATE | NAME          | CLASS    | SUB-<br>CLASS | FILING<br>DATE* |
|---------------------|------------------|----------------|---------------|----------|---------------|-----------------|
|                     | *5,665,386       | Sept. 9, 1997  | Benet et al.  |          |               |                 |
|                     | *5,716,928       | Feb. 10, 1998  | Benet et al.  |          |               | ·               |
|                     | *5,968,972       | Oct. 19, 1999  | Broder et al. |          |               |                 |
|                     | *6,004,927       | Dec. 21,1999   | Benet et al.  |          |               |                 |
|                     | *6,028,054       | Feb. 22, 2000  | Benet et al.  |          |               |                 |
|                     | *6,121,234       | Sept. 19, 2000 | Benet et al.  |          |               |                 |
|                     | *6,395,770       | May 28, 2002   | Broder et al. | <u> </u> | ·             |                 |

<sup>\*</sup> A copy is not enclosed since this application was filed after June 30, 2003.

## FOREIGN PATENT DOCUMENTS

| EXAMINER<br>INITIAL | DOCUMENT<br>NUMBER | DATE | COUNTRY | CLASS | SUBCLASS | TRANSLA-<br>TION |    |
|---------------------|--------------------|------|---------|-------|----------|------------------|----|
|                     |                    |      |         |       |          |                  |    |
|                     |                    |      |         |       |          | YES              | NO |
|                     |                    |      |         |       |          |                  |    |
|                     |                    |      |         |       |          |                  |    |

## OTHER DOCUMENTS

| EXAMINER<br>INITIAL | AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.  |
|---------------------|---|
|                     | M. P. Ducharme et al. "Disposition of Intravenous and Oral Cyclosporine after Administration with Grapefruit Juice," Clinical Pharmacology and Therapeutics, 57(5), 485-491 (1995)            |
|                     | C. Y. Wu et al. "Differentiation of Absorption and First-Pass Gut and Hepatic Metabolism in Humans: Studies with Cyclosporine," Clinical Pharmacology and Therapeutics, 58(5), 492-497 (1995) |
|                     | Physician's Desk Reference, (57th Ed. 2003), 2310-2313  |

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|                     | Physician's Desk Reference, (56th Ed. 2002), pp. 1129-1138   |  |  |
|                     | F. Akhlaghi et al., "Pharmacokinetics of Cyclosporine in Heart Transplant Recipients Receiving Metabolic Inhibitors," The Journal of Heart and Lung Transplantation, 20(4), 431-438 (2001)     |  |  |
|                     | Martindale: The Complete Drug Reference (33rd Ed., 2002) pp. 969-970   |  |  |
|                     | Wacher et al., "Peppermint Oil Increases the Bioavailability of Felodipine and Simvastatin," Clinical Pharmacology and Therapeutics, 71(2), P67 Abstract TPII-95                               |  |  |
|                     | M. M. Malingre et al., "The Effect of Different Doses of Cyclosporin A on the Systemic Exposure of Orally Administered Paclitaxel," Anti-Cancer Drugs, 12, 351-358 (2001)                      |  |  |
|                     | M. M. Malingre et al., "A Phase I and Pharmacokinetic Study of Bi-Daily Dosing of Oral Paclitaxel in Combination with Cyclosporin A," Cancer Chemotherapy and Pharmacology, 47, 347-354 (2001) |  |  |
|                     | S. N. DeWildt et al., "Glucuronidation in Humans. Pharmacogenetic and Developmental Aspects," Clinical Pharmacokinetics, 36(6), 439-452 (1999)   |  |  |
|                     | A. Lindholm, "Factors Influencing the Pharmacokinetics of Cyclosporine in Man," Therapeutic Drug Monitoring, 13(6), 465-477 (1991)   |  |  |
|                     | T. Prueksaritanont et al., "Glucuronidation of Statins in Animals and Humans: A Novel Mechanism of Statin Lactonization," Drug Metabolism and Disposition, 30 (5), 505-512 (2002)              |  |  |
|                     | Goodman and Gilman's: The Pharmacological Basis of Therapeutics, p. 13 (9th Ed., 1006)   |  |  |

F. 1.

| EXAMINER  | DATE CONSIDERED |  |  |
|---|-----------------|--|--|
| EXAMINER: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. |                 |  |  |